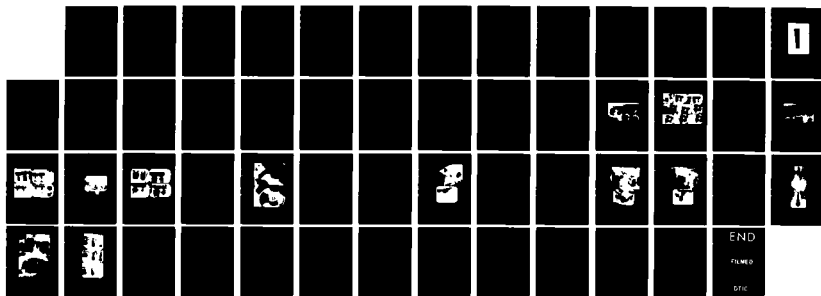


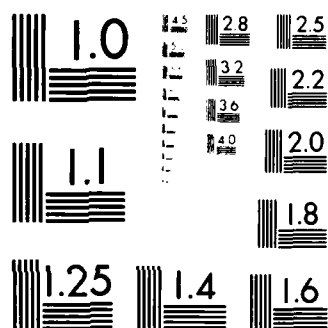
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Smith, R. L., 1980, *Robert L. Smith*,
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1. *Chlorophyll a* and *Chlorophyll b* were determined by the method of Arar and Collins (1971) using a Shimadzu 1601 spectrophotometer.

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REPORT NUMBER 12

SURGICAL TOOTH IMPLANTS, COMBAT AND FIELD

Annual Report

Craig R. Hassler, Robert H. Downes
Larry G. McCoy

July 15, 1982

Supported by

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| 20. ABSTRACT (Continue on reverse side if necessary and identify by block number) | | |
| <p>Long term implant studies of alumina tooth roots are being performed in both humans and baboons. The implants designed for this project are a single root rectangular design with serrations arranged for maximal stress distribution of occlusal loads. The implant is of a three-piece design. The serrated root portion is alumina ceramic. The upper two parts of the implant (post and core and crown) are conventional dental materials, usually gold.</p> | | |

Roots are produced by grinding bisque fired alumina stock on a computer controlled milling machine. This technique provides high quality, high strength, and design flexibility. A series of nineteen graded sizes of implants have been produced. Serration depth was selectively reduced in smaller implants to provide the necessary bulk of ceramic. Extensive quality assurance has been performed on the implants intended for human use. Quality assurance procedures include: wet densities, visual inspection, and mechanical testing of test bars. Modification of post and core design and its effect upon overall implant strength were evaluated.

Parametric-analysis of the implant in bone has been undertaken using the finite-element mathematical analysis techniques. Preliminary results indicate stresses under the serrations are within a range which should allow for maintenance of bone. There does not appear to be any unusually high areas of stress concentration, either in the implant or surrounding bone.

Long term implants are being followed in a colony of 8 baboons. A high success rate has been maintained, as reported previously. Some implants have been functioning successfully for seven years. The animals appear to severely stress the implants thus providing an extreme test for the implants. There have been some fractures of ceramic roots in the baboons. The fractures have been isolated to one batch of ceramic roots produced in 1976. Since that time, improved ceramic processing techniques have dramatically increased the flexural strength of the implants. This improvement minimizes the probability of future fractures.

In human patients, implants have been attempted using three different techniques. Of the three techniques, repeatable and satisfactory results appear to be obtainable when the implant is placed flush with the alveolar bone. This technique apparently isolates the implant sufficiently from mechanical stresses so that ingrowth into the implant serrations can occur. The implants placed in anterior maxillary areas appear to have a higher probability of success than those placed in posterior mandibular areas. If the implant remains rigidly fixed in bone throughout the ingrowth and reconstruction phase, long-term prognosis for implant success is excellent. Consequently, initial ingrowth is the most critical phase of the implant procedure.



SURGICAL TOOTH IMPLANTS, COMBAT AND FIELD

by

Craig R. Hassler, Robert H. Downes, and Larry G. McCoy

SUMMARY

Long term implant studies of alumina tooth roots are being performed in both humans and baboons. The implants designed for this project are a single root rectangular design with serrations arranged for maximal stress distribution of occlusal loads. The implant is of a three-piece design. The serrated root portion is alumina ceramic. The upper two parts of the implant (post and core and crown) are conventional dental materials, usually gold. Roots are produced by grinding bisque fired alumina stock on a computer controlled milling machine. This technique provides high quality, high strength, and design flexibility. A series of nineteen graded sizes of implants have been produced. Serration depth was selectively reduced in smaller implants to provide the necessary bulk of ceramic. Extensive quality assurance has been performed on the implants intended for human use. Quality assurance procedures include: wet densities, visual inspection, and mechanical testing of test bars. Modification of post and core design and its effect upon overall implant strength were evaluated.

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FOREWORD

This study has been conducted at Battelle's Columbus Laboratories utilizing the staff and resources of the Health and Environmental Sciences Section and the Ceramics Section. The clinical portion of this study has been conducted at The Ohio State University College of Dentistry.

This is the twelfth report of progress under Contract No. DAMD-17-82-C-2020, "Surgical Tooth Implants, Combat and Field". The principal investigator for this research was Dr. Craig R. Hassler. Ceramics research was directed by Mr. Larry G. McCoy. The human studies have been under the direction of Dr. Robert H. Downes and have been conducted in the clinical facilities of the Ohio State University College of Dentistry. Clinical research was conducted under a protocol approved by The Ohio State University Human Subjects Committee. This research has been performed in accordance with an investigational device exemption obtained from the FDA. Animal research, conducted at Battelle-Columbus has followed the guidelines of the "Guide for Laboratory Animals Facility and Care" as promulgated by the Committee on the Guide for Laboratory Animal Resources, National Academy of Sciences, National Research Council.

QUALITY ASSURANCE STATEMENT

This study was inspected by the Quality Assurance Unit and reports were submitted to management and the principal investigator as follows:

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BACKGROUND

In the last several years a new generation of dental implants has evolved. These devices are designed to be rigidly affixed by bone ingrowth and provide minimization of stress usually by serrations⁽¹⁻⁴⁾ or pores.⁽⁵⁻⁶⁾ Generally, these implants are designed as single freestanding prostheses. Several biocompatible materials have been utilized including plastics,⁽⁷⁾ metallics⁽⁶⁾, and ceramics.^(1,2,3,8-18,22-24,26-29) Our laboratory has specialized by using alumina (Al_2O_3) ceramics incorporating a serrated design. In the past 11 years we have developed a combination of material, design, and technique components which appear promising. It should be noted that all three components (design, material and technique) are of importance if an implant system is to be successful. Failure of any one of the three components can be detrimental. A serrated ceramic implant system based upon these principles is under test in our laboratories. Implant experience in animals exceeds 6 years of function. On the strength of the animal experiments, a clinical study was undertaken to evaluate how much of the technology was relevant to the human situation.

The lower portion of our three-piece implants are produced from alumina (Al_2O_3) (Figure 1). This portion has large serrations into which bone ingrowth has been demonstrated.⁽⁴⁾ The implant illustrated in Figure 1 has smaller serrations at the crown end of the root to increase the strength of smaller sized roots in these critical areas. The upper two portions of the implant: post and core and crown - are cemented after ingrowth to allow function. The three-piece design allows minimization of occlusal stresses and strains on the implant to facilitate bone ingrowth. An analogous situation is seen in the healing of long bone. It is assumed that, as in long bone, an orderly transition through a sequence of gradually stiffer bone materials proceeds (hematoma → connective tissue → woven bone → compact bone). The maximal strain which any of these tissues can withstand must not be exceeded if healing is to proceed to completion.⁽²¹⁾ Consequently, strain upon the implant-bone interface must be minimized early in the healing process if bone formation is to occur. Once the implant is stabilized by ingrowth, the large implant surface area at right angles to the principal load axis of the implant

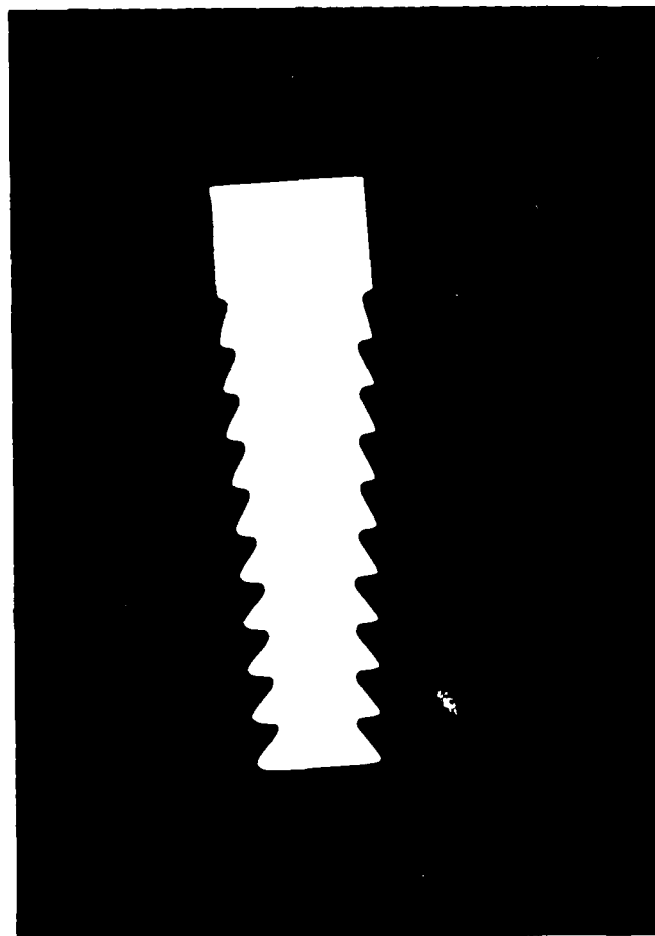


FIGURE 1. SERRATED ALUMINUM OXIDE DENTAL IMPLANT

This photograph shows a rectangular root with smaller serrations at the top for increased strength. Not visible is the post hole in the center of the implant. A prefabricated post and core is cemented into the hole. A clinical crown is then cemented to the post and core.

is intended to maintain bone stresses below a level which produces resorption of bone. Attempts to quantify these stresses have been made in this laboratory.⁽⁹⁾ This information is not specifically for alveolar bone; however, it serves as a guide in an area where no direct information is available. As demonstrated by histologic data collected on this project⁽²⁾, the hypothesis appears to be viable and bone can exist successfully in direct contact with a functional implant.

The above mentioned parameters, unique to this design, are the serrations and three piece construction. They are the two major determinants for design success. A secondary design parameter which has proven useful is the use of a size graded series of implants. This gradation allows optimal fit into the available site. Nineteen sizes have been produced for the clinical studies. In practice several of these sizes are not used, but they are available when required. Both rectangular and elliptical implants were used in the baboons. However, the rectangular shape appeared to provide a better initial fit. Consequently, this design is being used exclusively in human clinical trials. The method of producing roots by contour grinding, on a computer controlled milling machine, has allowed for flexibility not only in size, but in other design changes. In a research protocol, this ease of flexibility has been an asset and will continue to be our method of root manufacture.

At this time, the long term implant success in animals is encouraging. Success for a similar, or longer time span in humans is necessary to determine the true success of the implant.

METHODS

Fabrication of Tooth Roots

The various sizes of implants commonly used for this project are shown in Table 1. The powder used for fabrication is Reynolds Aluminum Company's RC-HP-DBM. This is a high purity, dry ball milled powder having a median particle size of approximately 0.5 microns. The vendor data is summarized in Table 2 and are generally found to be accurate.

TABLE 1. COMMONLY USED TOOTH ROOT SIZES (MILLIMETERS)

| | | | |
|------------|------------|------------|------------|
| 4 x 4 x 15 | 5 x 5 x 15 | 6 x 6 x 15 | 7 x 7 x 15 |
| 4 x 5 x 15 | 5 x 6 x 15 | 6 x 7 x 15 | 7 x 8 x 15 |
| 4 x 6 x 15 | 5 x 7 x 15 | 6 x 8 x 15 | 7 x 9 x 15 |
| 4 x 7 x 15 | 5 x 8 x 15 | 6 x 9 x 15 | |

The methods for production of the tooth roots has been reported previously^(27,28). Briefly, the processing procedure used is as follows:

- (1) Hydrostatic pressing granulated material at 50,000 psi to form preform rods nominally 125 mm long by 14 mm diameter
- (2) Bisque firing preform rods at 1120 C for 2 hours
- (3) Contour grinding tooth roots
- (4) Hand finishing tooth roots
- (5) Final sintering at 1540 C for 1-1/2 hours.

TABLE 2. ALUMINA POWDER DATA

| Material
Designation | Sample No. | Alk | Purity | | Metals | Particle
Size
% \leq 1 |
|------------------------------------|--|---|--------|-------------------|--------|--------------------------------|
| | | | MgO | SiO ₂ | | |
| RC-HP-DBM
(8-15-80, Lot 2) | 80-314 | .026 | .050 | .018 | .016 | 89.3 |
| Surface Area
m ² /gm | Pressed Density ^(a)
gm/cm ³ | Sintered Density ^(b)
gm/cm ³ | | Shrinkage Percent | | |
| 7.4 | 2.20 | 3.96 | | 18.0 | | |

(a) Pressed at 5000 psi.

(b) Sintered at 1510 C, 2 hours.

A quality assurance program is utilized on all roots destined for clinical trials. The details of this program have been published in our previous reports^(27,28). Briefly, this program consists of:

- (1) A method of traceability which allows each root to be identified as to raw material, size, and time of manufacture.
- (2) Manufacture of test bars, which are produced for each batch of roots. Presently flexural strengths exceeding 70,000 psi are being obtained.
- (3) Microscopic examinations of each root by both transmitted and reflected light.
- (4) Wet density measurements of representative implants from each group.

Investigational Device Exemption Application

To place this study in compliance with 1976 modifications of the Pure Food Drug and Cosmetic Act, application for an Investigational Device was made to the FDA. This Exemption (IDE) allows clinical research of

experimental devices that have not yet been commercially produced. The exemption provides necessary freedom for a product to be adequately evaluated. Strict reporting requirements are placed upon the investigators. The clinical data collected must be reported to the FDA at least annually. This exemption does not supplant the authority of the local human subject committee. The various reporting requirements required by the FDA have been complied with. The project has been reviewed and approved annually by the Ohio State University Human Subjects Committee. The requested exemption was obtained for this project in January of 1980.

Baboon Implant Procedures

Animal implant procedures have been performed in the adult, female baboon. Typically, following extraction the tooth socket, either molar or pre-molar, was shaped using a bone burr. A socket was formed by a continual fitting procedure. The root was firmly tapped into the alveolar bone until almost flush with the bone. The root was given no further attention, however, the animal received prophylactic antibiotics immediately post-surgery and a soft diet for two weeks. The root implant site was observed periodically for three months. Radiographic examination and manual palpation indicated if the root was adequately stable for reconstruction. A similar procedure was used to implant roots in edentulous sites.

Restoration of the implants was facilitated by prefabrication of a gold post and core prior to implantation. Following adequate stabilization by bone ingrowth into the serrations (at approximately 3 months), the post and core was cemented into place. Impressions were taken. A gold crown was fabricated and cemented into place. Care was taken to provide correct occlusion. The implant is periodically examined and documented by radiographs and photographs. Clinical chemistry, hematology, and parasite analyses are performed at the same intervals. It should be noted that most baboon roots were implanted prior to the time period covered by this report.

Baboon Husbandry

The eight animals being evaluated are individually caged in one room of the Battelle-Columbus animal facility. The animals are fed Purina monkey chow twice daily. One daily meal consists of the chow pre-moistened and softened, whereas the other meal is the same chow in the as-received dry state. Water is ad libitum, via drinking bottles. The room environment is maintained on a 12-hour light/12-hour dark cycle. Temperature is maintained between 72-76 F. Humidity is maintained between 40-60 percent RH. Visual observations of the animals are recorded twice daily. Any unusual observations are reported to the veterinarian in charge and the principal investigator. For evaluation procedures the animals are tranquilized with Ketamine® prior to removal from their cages.

Human Implant Procedures

Rectangular implants are placed in edentulous, or fresh extraction sites. Roots are placed where they will function as single free-standing implants when reconstructed. Under local anesthetic, implant sites are prepared using bone burrs placed in a low-speed contra-angle air turbine hand-piece with sterile saline cooling. A continual fitting procedure is used. Final placement of the implant is via tapping with a mallet to provide a stable interference fit. The root implant site is observed visually and radiographically throughout the study. Normally a gold post and core is prefabricated for each implant. The patients are observed periodically until the implant is rigid or exhibits minimal motion. At that time, the post and core is cemented and a clinical crown fashioned. Periodic examination of the patient continues following reconstruction. All clinical studies are performed at The Ohio State University College of Dentistry, in compliance with a protocol approved by the Ohio State University Human Subjects Committee and the FDA Bureau of Medical Devices.

Three variations of implant technique have been employed: In the first group, implants were surgically placed so that the uppermost serration was just covered by the crest of the alveolar ridge. Consequently, about 3 mm

of implant was left protruding above the ridge. The first 25 patients were implanted in this fashion.

A second group of six patients' implants were prepared with integral post and cores. The implants were partially isolated from occlusal loads by orthodontic stay wires attached to adjacent dentition and a methacrylate resin cap over the top of the implant.

A third group of seventeen patients was prepared in which the top of the root was placed flush with the alveolar crest. Whenever possible a muco-periosteal flap was placed over the top of the implant. This flush implant technique is the only one presently in use. Both anterior maxillary and posterior mandibular sites have been used.

RESULTS

Animal Studies

During the last year, long-term observation of implants continued in nine baboons. Again, as was observed in previous years, the failure rate has been low. Presently 37 roots are being followed in the baboons. Twenty-four of these roots are now "successfully" in function. In the last 6 years, 8 roots have fractured after reconstruction. All of the fractured implants were from the same batch manufactured in 1976.

Roots in function are considered "successful" by the following criteria:

- (1) Radiographic appearance of dense bone ingrowth into serrations
- (2) Resistance to movement by manual palpation (rigid)
- (3) Minimal gingival irritation
- (4) Maintenance of function and/or occlusion.

Roots which have remained rigid, but have not been put into function are termed "potentially successful" until they are reconstructed. All "successful" roots in this study were implanted a minimum of 3 months before reconstruction.

In the 9 animals, the following history of functional success has been observed to date:

| <u>Number of Roots</u>
<u>(in all 9 Baboons)</u> | <u>at</u> | <u>Approximate Time</u>
<u>in Function, yrs</u> |
|---|-----------|--|
| 4 | | 6-1/2 |
| 1 | | 5 |
| 11 | | 4-1/2 |
| 2 | | 4 |
| 3 | | 3 |
| 3 | | 2 |
| Total | <u>24</u> | |

When compared to the results of last year (28), it is evident that two implants were lost during the year. Again as in the past, these losses were implant fractures. The fractured implants were from the same batch

manufactured in 1976 which has been responsible for all fractures. It is significant to note no other implants produced, either before or after 1976, have fractured.

The analysis of the data has been complicated by the death of one baboon. The details of this incident will be included in a subsequent section of this report. Implant failure was not involved in this animal's death. The implants from that animal are included in the data.

Another complicating factor is the wear on several of the gold crowns, which has taken some implants out of occlusion. In addition, two clinical crowns have been lost leaving only the post and core. The baboons apparently abuse their dentition as evidenced by the extreme wear seen in these instances. The animals routinely chew on their metal cages as evidenced by metallic aluminum on their teeth. This activity probably explains the accelerated crown wear. Even though detrimental to the crowns, this harsh test illustrates an effective evaluation of the bone ceramic interface.

The analysis of the data depends upon whether one wishes to be pessimistic or optimistic. For example with an optimistic analysis, only one ingrown and reconstructed root has become mobile and eventually failed; post reconstruction with this analysis one could claim a success rate of 40 of 41 or 97.56%. On the other hand if one excludes every implant that is not in perfect occlusion (18 of 41) or 44% would be considered successful. Obviously neither example is realistic. A more realistic approach would be to include as "potential successes" implants worn out of occlusion, fractured implants, and those functioning with post and core only. With this type of analysis only 5 implants would be considered truly failures. This would yield a success rate of 36 of 41 or 88% potentially successful implants. It is interesting to note that 4 of these five failures occurred early in the baboon studies (1975-77). All of these failures were in fresh extraction sites. With one exception, these sites were reused as edentulous (or healed) sites and went on to have an implant successfully rigid. The early occurrence of these failures strongly suggests an experience and/or technique improvement factor. The baboon data is skewed towards fresh extraction sites (33 of 41), consequently, it is impossible to ascertain if there is any preferential success relative to type of implant site (fresh vs. healed).

The one implant which became mobile after reconstruction followed a unique course. This implant was allowed to remain functional to assess the fate of mobile implants. Twice during its history, as the implant migrated into occlusion, crown height was reduced. Mobility was noted continually for 4 years and 15 weeks. Approximately 15 weeks after that observation the root fractured, leaving two serrations in the mandible. The site went on to heal normally. The root fragment appears to be totally encased in bone.

Throughout this study gingival health around the implants has remained typical for baboons. However, bleeding often can be elicited from the sulcus upon probing. This bleeding appears to be periodic, possibly associated with the menstrual period of the animals. It is significant to note that no obvious infections, other than the mild gingival inflammation typical of baboon dentition has been noted.

Early Death

On February 26, 1982, baboon 714 died following an illness of relatively short duration, and despite an effort to save the animal. A ceramic root had been recently implanted on 12-10-81 utilizing the buccal flap technique. The baboon was placed on prophylactic antibiotic therapy and a soft diet, which is standard procedure following implant surgery. Daily observations disclosed the baboon was eating little, which is not uncommon following surgery, so fruit was supplemented to its diet as an inducement to increase food intake. However, the low level of consumption continued. The animal's condition deteriorated, so a physical examination was performed on 12-16-82 to determine the cause. The physical examination disclosed that the animal had torn off the buccal flap covering the most recent root implant. Antibiotic therapy was immediately resumed and additional tests were performed, but the baboon's condition continued to deteriorate until it finally died. The gross necropsy of the baboon gave inconclusive evidence as to the cause of death. The histopathology evaluation of major organ systems following necropsy indicated systemic septicemia as the probable cause of death. The point of origin of the infection was not ascertained.

The mandible, containing implants was removed at the time of necropsy for radiographic and histologic evaluation. Two "successful" functioning gold crowns (one elliptical and one rectangular root) and one fractured elliptical root, plus the most recent rectangular root implant were retrieved for future study. The time in function of the functional implants was 4+ and 3+ years respectively. Total implant time for three of the implants was 4+ years, and for the most recent implant time was 7 weeks. Visual examination of this recent implant revealed an open cavity extending distally from the implant approximately 1 mm. This cavity extended vertically along most of the implant length. Since this animal had sloughed its rather large periosteal flap, this cavity described above was potentially exposed to the oral environment for an extended period. Consequently, this cavity was a potential source for bacterial invasion. Further investigation of this cavity is planned.

Clinical Examples of Baboon Dental Implants

Figure 2 shows the clinical view of two posterior mandibular implants which have been in place for 6.6 and 6.98 years. These implants have been in function for 6.2 and 6.6 years. Distal to the two implants is an edentulous site from which an implant was lost shortly after being placed in a fresh extraction site. A thickened gingival cuff can be observed about the implant. This is common on the buccal side of multiple baboon implants. Burnish marks on the crowns indicate extreme wear of occlusal surfaces. The baboons are often observed chewing on the bars of their cages. Presumably, this activity is responsible for the wear.

Figure 3 is a collage of radiographs for the same implants shown in Figure 2, spanning from March of 1976 to March of 1982. The first radiograph is 9 months after placement of the mesial implant (shown with post and core) and four months after placement of the distal implant (without post and core). Note that the serrations are readily visible. By December of the same year, a significant increase in bone density about the implants can be noted (see second radiograph). This density increase is interpreted as a response to the functional stresses placed upon the implant. Such alterations are consistent

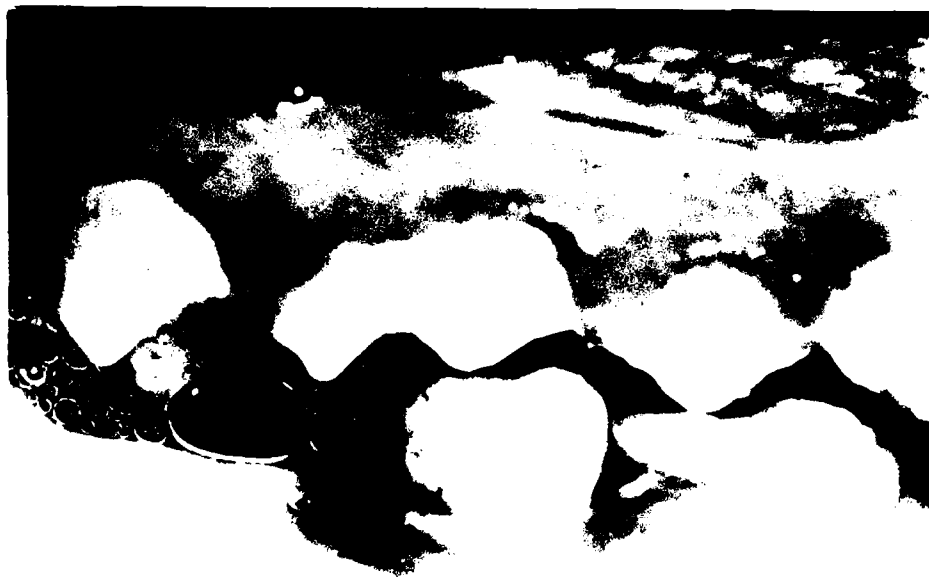


FIGURE 2. CLINICAL PHOTOGRAPH OF A29 AND A30 IN BABOON 469

These particular implants have been rigid and in function for 6.2 and 6.6 years. The crowns exhibit extensive wear.

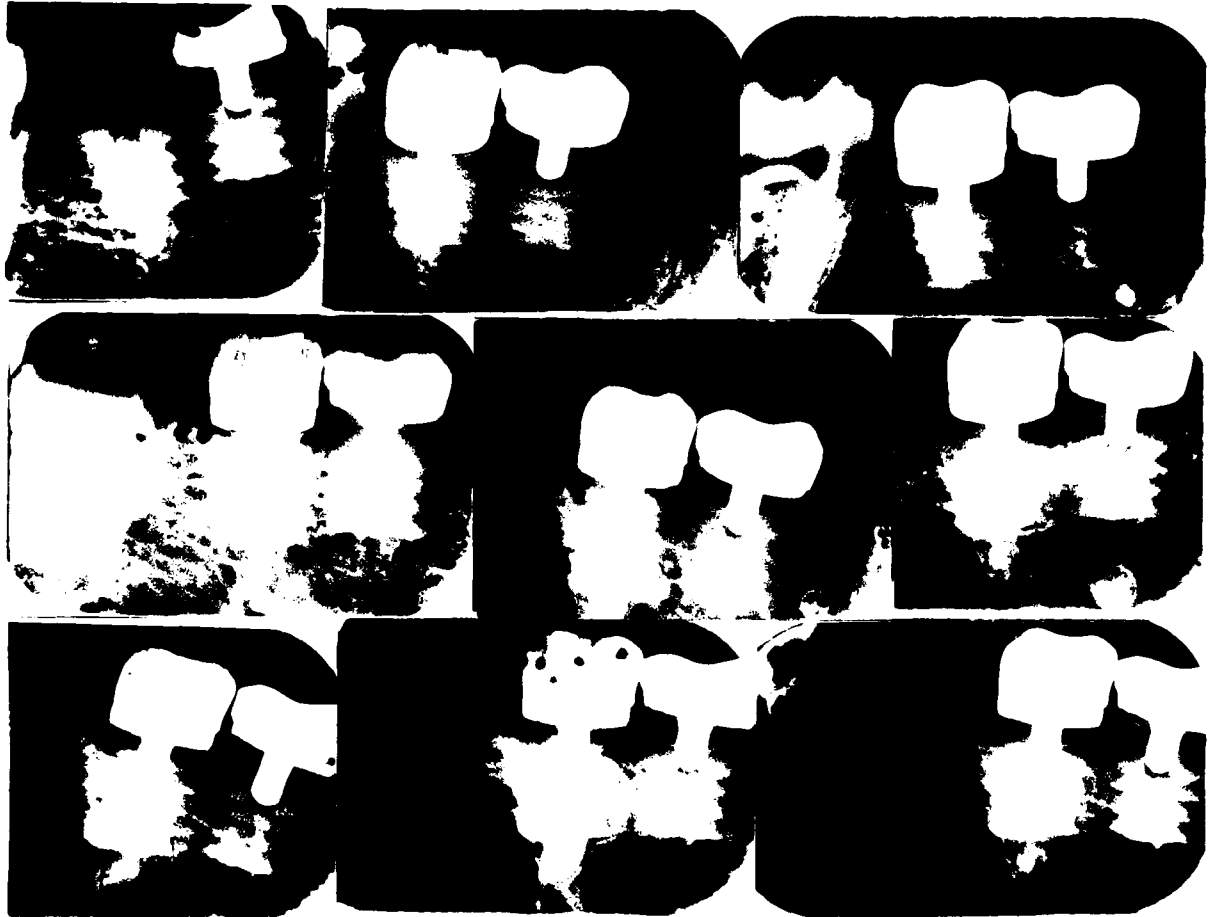


FIGURE 3. RADIOGRAPHIC HISTORY OF IMPLANTS IN BABOON 469

These 9 radiographs are in sequential order, from top left to lower right. The areas shown are A29 and 30, which are the same areas as shown in Figure 2. The dates of the radiographs are: 3/2/76, 12/15/76, 1/4/77, 1/19/77, 1/5/79, 6/27/80, 3/19/81, 9/24/81 and 3/17/82. An increase in bone density with time can be noted around the serrations. The extraction of a distal molar, and subsequent failure of an implant in that site appears to have precipitated loss of some alveolar bone height.

with Wolf's law of bone remodeling⁽²¹⁾. Throughout the rest of the series of radiographs the density continues to obscure the serration detail. The placement of an implant in the distal molar site (fourth radiograph) appears to precede the loss of some alveolar bone height, as evidenced in the fifth and sixth radiographs. Alveolar bone height appears to remain stable from early 1979 (fifth radiograph) to March 1982 (last radiograph).

Figure 4 shows three implants, two of which have been implanted in a baboon for 6.8 years and in function for 6.5 years. The distal implant shown to the right in this view has lost its clinical crown. This implant has been in for 4.95 years. All of these implants have remained rigid. Extreme wear on the crowns has caused spots on the occlusal surfaces of the crowns to be burnished. A thickened band of gingival tissue can be observed about the mesial two teeth (to the left in this figure).

Figure 5 shows four different radiographic views of the implants shown in Figure 4. The radiographs cover the period from March 1976 through March 1982. The bone surrounding the implant appears quite dense in the first view. The roots have been in function for 6 months and radiographic detail of the serrations is already obscured. In the subsequent views removal of the distal molar apparently affected the vertical alveolar bone height of the two previously placed implants. The third radiograph shows an implant in the distal molar site. The fourth radiograph shows 2 mm of cratering around the implant. The bone around the proximal two implants appears to increase in density, perhaps in response to the loss of vertical bone height. This cratered implant was placed in a healed site, after a previous attempt to place an implant in a fresh extraction site failed five months earlier.

Figure 6 is the clinical view of two mandibular implants in a baboon, 4.88 years following implantation. These roots have been in function for 4.44 years. As in the previous example, a gingival cuff can be seen. These implants have remained rigid.

Figure 7 is a collage of radiographs for the same baboon as shown in Figure 6. The first radiograph is three months post implant. Some vertical bone loss can be noted since the implants were originally implanted with the first serration flush with alveolar bone height. The second radiograph is at

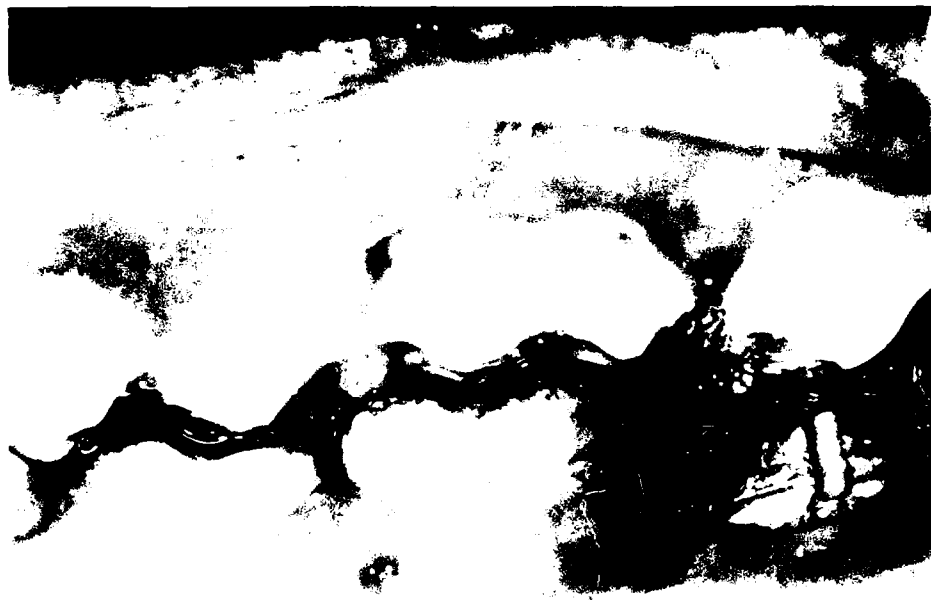


FIGURE 4. CLINICAL PHOTOGRAPH OF A18, A19, AND A20 IN BABOON 469

The mesial two implants have been in function for 6.5 years. The crowns exhibit wear and the gingival cuff often seen on multiple baboon implants is present. The distal implant has lost its clinical crown, but remains functional with only post and core.

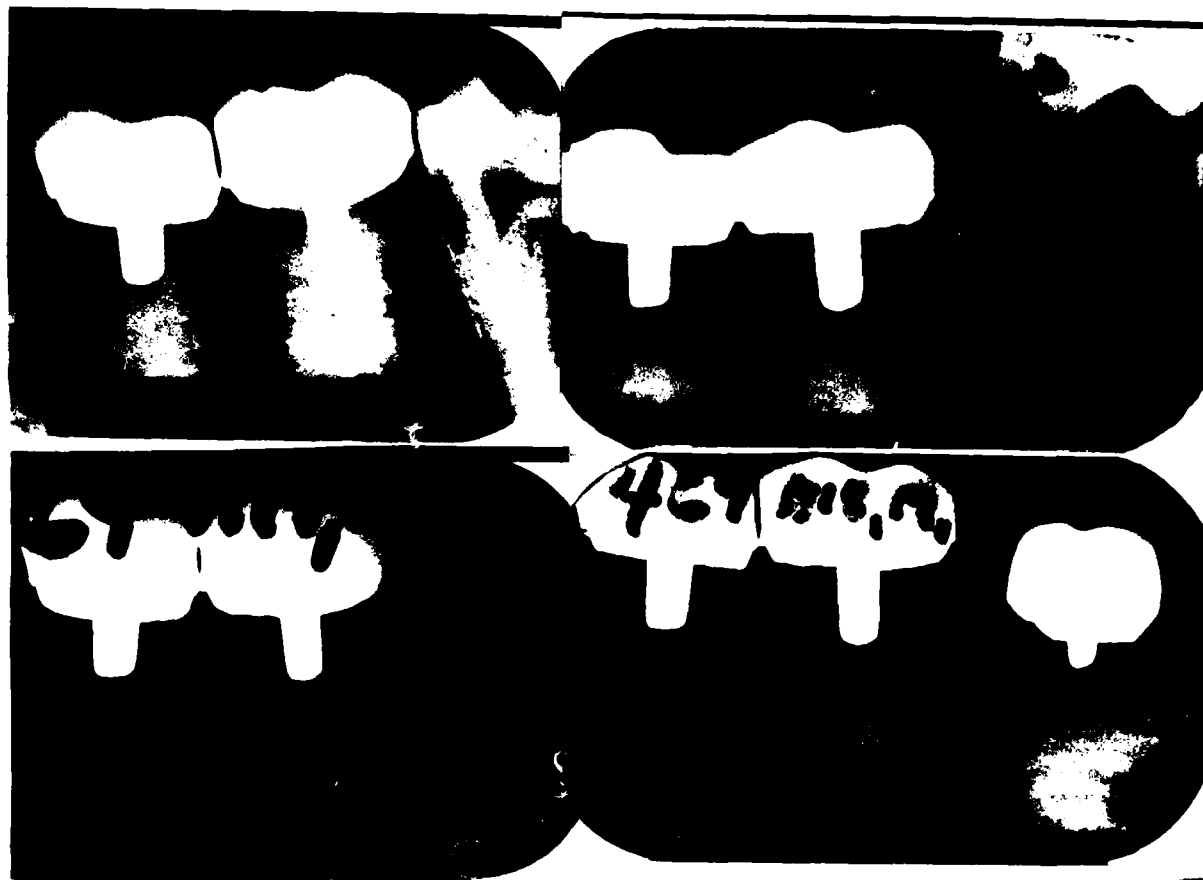


FIGURE 5. RADIOGRAPHIC HISTORY OF A18, A19, AND A20 IN BABOON 469

These radiographs, from upper left to lower right are dated: 3/2/76, 3/30/77, 11/5/79 and 3/17/82. The last radiograph is the same date as the clinical photograph in Figure 4. By the time of the first radiograph, bone is dense around the implants. The following radiographs show the events following extraction and implantation of a third root. These events precipitated a loss of alveolar bone, but the implants all remain stable despite this bone loss. Difficulties with filling a crown, and multiple procedures performed to properly fit a crown on A18 might be responsible for the large vertical bone loss around that particular implant.



FIGURE 6. CLINICAL PHOTOGRAPH OF IMPLANTS IN A29 AND A30 OF BABOON 713

These implants have been in function for 4.44 years. They exhibit both crown wear and the gingival cuff often seen in baboon implants. The implants are rigid and functional.

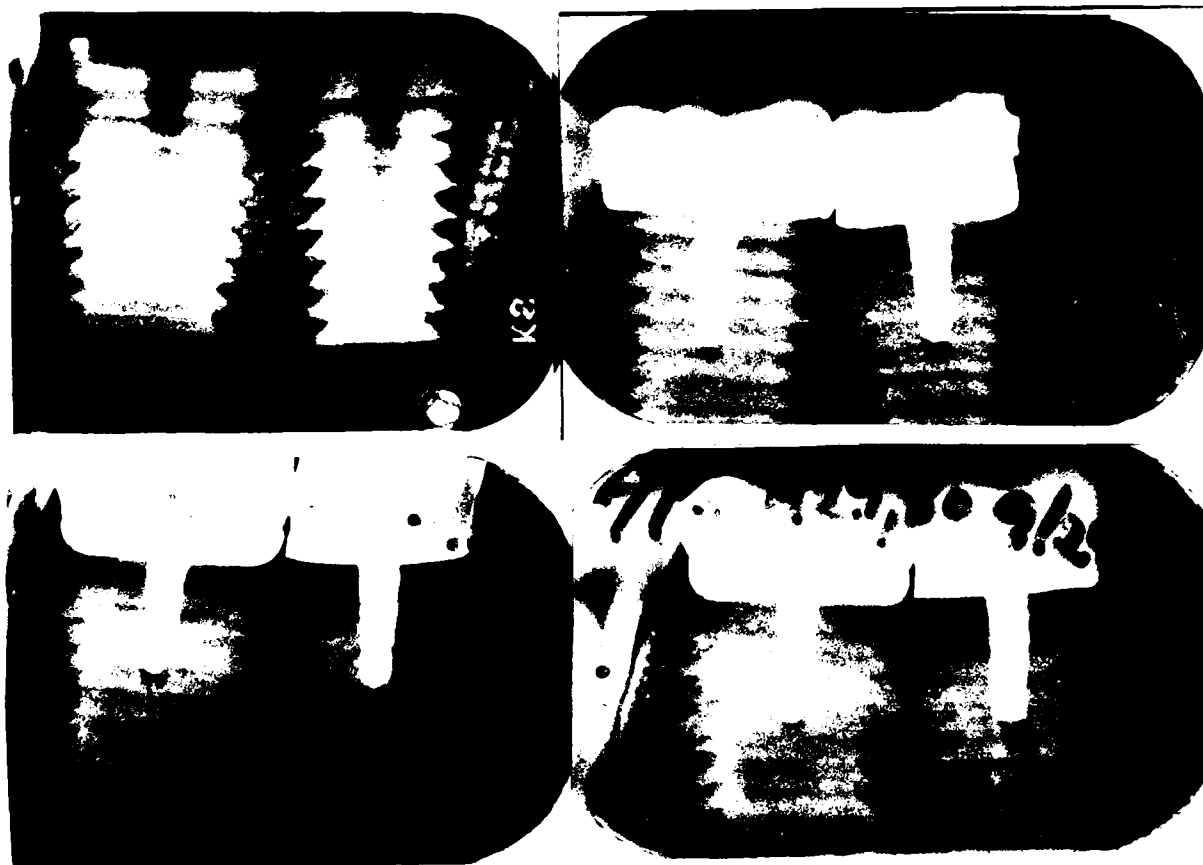


FIGURE 7. RADIOGRAPHIC HISTORY OF IMPLANTS IN A29 AND A30 OF BABOON 713

These radiographs, from upper left to lower right, cover the dates: 11/23/77, 8/30/79, 3/19/81, 9/24/81. This series shows the typical increase in bone density, which obscures the serration detail. In these implants alveolar bone height is maintained. The increase in bone density appears mostly at the crest of the alveolar ridge.

6 months post reconstruction. At this time, an increase in bone density is not as obvious as in the previous examples. However, a band of denser bone can be noted near the crest of the alveolar ridge. One and a half years later, this band of bone appears even denser. There has been no apparent loss of alveolar bone height, but a definite increase in density in this area. The last radiograph (6 months after the third radiograph) indicates the same dense band of bone. The radiograph suggests an observation similar to previous baboon experiments, in which histologic analysis typically revealed connective tissue in the top most serration.

These radiographs show that bone is not present in the top most serration. It is interesting to note that bone density did not increase dramatically along the whole length of the root as indicated in the two previous examples, but bone density increased preferentially near the alveolar crest. These implants are longer than those used in the previous example. They also have more stress distribution area. This observation is consistent with Wolf's law of remodeling, if the same load is being placed upon the implants in both situations, one would expect less dense bone around the implants with larger stress distribution area.

Figure 8 is the clinical view of a maxillary lateral implant in a baboon. Both the buccal and lingual view of the reconstructed implant are shown. This implant has been in place for 2.37 years, and in function for 1.9 years. This implant has been vigorously stressed by the animal as evidenced by the aluminum deposits on the crown, from continual cage chewing. This anterior implant has held up well, despite the protrusive and unprotected nature of this implant site. Very few anterior sites were attempted in the baboon because they anatomically bear little resemblance to the human.

Clinical Chemistry and Hematology Results in Baboons

Throughout the project history hematology and clinical chemistry data have been collected on all animals, at approximately 3 month intervals. The data for all animals has been compared to control (pre-implant) data. To date no value has shown an apparent significant alteration from baseline. Values from animal 711 which periodically has low hematocrit values is an



FIGURE 8. CLINICAL PHOTOGRAPHS OF IMPLANT A7 OF BABOON 713

These photographs show both buccal and lingual views of an upper anterior implant. The silver discoloration on the crown is aluminum from the cage bars, which the animals frequently chew, severely stressing the implant.

exception. The parameters measured are: Glucose, BUN, Chloride, Bilirubin, Alk. phos., SGOT, SGPT, Creatinine, Na, Ca, Mg, K, Hemoglobin, Hematocrit, WBC, RBC, MCV, BANDS, SEGS, EOS, BASO, Lymph, Mono, Platelets, Retic and Pro-time. At the termination of the animal experimental phase, a more complete analysis of this data is planned.

Clinical Studies

The clinical portion of this project has involved the implantation of rectangular ceramic roots in 48 patients. The clinical study commenced in August, 1978. The roots have been implanted using three different techniques. In the first 25 patients, roots were implanted in mandibular areas with the first (or uppermost) serration flush with the alveolar crest. This implant height was dictated by the post and core design, in which the gold overlaps the outside of the root structure and extends downward into the gingival sulcus. In the human, the implant was placed high enough to allow post and core seating without bone removal. Hence, the implant was placed higher than in baboon studies. The high success rate in baboons, even when the implants were left to protrude slightly above the alveolar bone level, gave us confidence that in the "cooperative" human subject this procedure would be acceptable. In the first 25 patients, mandibular molar and premolar sites were used. Seventeen were healed sites and 8 were fresh extraction sites. All implants were periodically observed by clinical observation and X-ray. All implants were rigid at the time of surgery, by virtue of the interference fit produced by tapping the implant into place. All implants exhibited some degree of buccal-lingual mobility within the first 1 to 3 months post-implant. The degree of mobility and the cause of the increase in mobility was highly variable, but typically 1/2 mm or less mobility was observed within that time period. Sixteen of the 25 patients exhibited a subsequent decrease in mobility with time. Of the original patients, six are still in function with buccal-lingual mobility ranging from 0-3/4 mm. The average implant time in these patients is 3.54 years. The average restoration time is 2.54 years. The longest implant time is 3.92 years.

There have been some notable successes in this group. Some patients' implants have become totally rigid and appear to be identical to the baboon studies in their clinical course. Figure 9 is an example of one such implant. This posterior mandibular implant has been implanted for 3.67 years and in function for 2.83 years. The clinical appearance of the implant (Figure 9A) has remained stable throughout the study. The radiography (Figure 9B) demonstrates a situation similar to that seen in the baboon studies. That is, increased bone density obscuring the serration detail to some extent. There has been no formation of a radiolucency about the implant. There has been a modest loss of vertical bone height, since the uppermost serration appears to be filled with connective tissue. The bone height appears to be remaining stable. This particular implant exhibited some buccal-lingual mobility early in its course, but the implant became completely stable prior to reconstruction. This reduction of implant mobility, clearly observed in at least two patients indicates that stability can be regained, however, this is probably the exceptional case.

Of the failed implants in this group, 12 were restored and 5 failed prior to restoration. In the restored group of failures, average implant time till failure was 2.06 years. The range of time to failure was 1 year to 3.13 years. With the unrestored implants, the average implant time at failure was 1.35 years. The range of nonrestored failure time was 2 weeks to 2.25 years.

The typical failure process observed was a slow increase in mobility over two years. When mobility reached 1 mm buccal-lingual, with rotation present, the implant was removed to prevent unnecessary bone loss. Two patients had infection noted at implant removal time. Seven patients near removal time indicated some degree of soreness when biting hard. Generally gingival health remained excellent in all patients regardless of the state of failure. Most patients utilized the implants as functional and aesthetic devices up until the time of removal. Several patients had to be convinced of impending implant failure, since they were satisfied with the devices. All patients with implants removed have gone on to heal uneventfully. Two patients have not been available for follow-up, consequently, their present implant status is unknown.

In view of the difficulty of obtaining stability in the first group of patients, the next series of six patients were performed using orthodontic

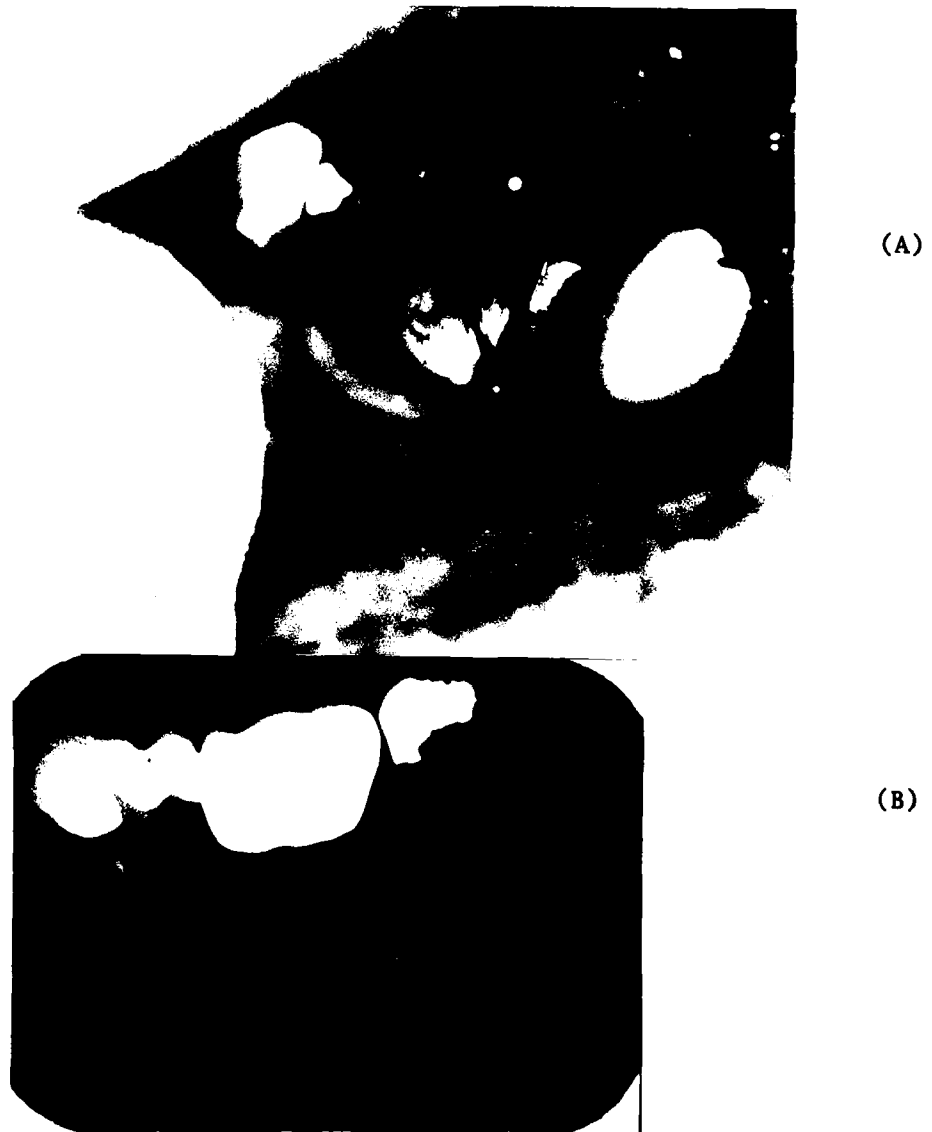


FIGURE 9. CLINICAL PHOTOGRAPH AND RADIOGRAPH OF POSTERIOR MANDIBULAR HUMAN IMPLANT

This is an example of a success from the first group of patients where the root was allowed to protrude above the alveolar bone during ingrowth. Despite this poor technique, the root has become rigid, there has been minimal bone loss, the bone density has increased around the implant, gingival health is excellent and the prosthesis is functional. This implant has been in function for 2.83 years.

devices to stabilize the implant to adjacent teeth. Orthodontic bands were fitted to adjacent teeth and connected by wires. An acrylic cap was fitted over the top of the implant to support and protect the implant.

The patients were implanted in the posterior mandibular areas, 5 in healed sites, and 1 fresh extraction site. The fresh extraction site implant never stabilized and was never restored. The implant was removed at 35 weeks post-surgery when rotation was observed.

Four of the healed site implants remain in function, but they all exhibit approximately 1/2 mm of buccal-lingual mobility. The average implant time in this group is 2.06 years, with a range of 1.94 years to 2.17 years. The average restoration time is 1.4 years. The one functional failure in this group occurred after being implanted for 1.75 years and functional for 1.27 years. Even though these implants are functional, aesthetic, and well accepted by the patients, they are a less than optimal result. Our previous experience indicates that the long term prognosis for these implants is poor. One should anticipate that these implants will all eventually fail. However, the time to failure may be longer than in group one, since the mobility of implants in this group is not changing dramatically.

In light of the less than optimal results of the previous research groups, a third group of patients was started. This group was to assess if a deeper placement of the root would offer additional protection from mechanical "stress" and allow the initial mechanical stabilization of the implant to proceed to a long term rigid situation; as commonly observed in baboon studies, but infrequently observed in prior human studies. The implant design as utilized in group one studies prevented flush placement of the implant. Since bone and attached gingiva would have to be removed to seat the overlapping post and core; the gold overlap (or coping) was removed, thus creating a post and core flush with the exterior surface of the alumina. Mechanical testing indicated that this removal of coping did not reduce the mechanical strength of the root-post and core attachment⁽²⁸⁾. Consequently, post and cores for group three studies do not have an overlapping gold coping. Additionally, the ceramic root portion has been modified to facilitate flush placement. Specifically the nonserrated portion at the top of the root has been reduced to 2 mm, with the exception of the smallest 4 mm x 4 mm implant

where this dimension is 3 mm. This exception is to provide adequate thickness of ceramic within the implant. In this small implant the thickness of ceramic between the post hole and the top most serration might be too thin if this exception to the design were not made. The validity of this assumption is presently being assessed by mathematical modeling of the implant.

To date, 17 patients have been implanted in both fresh and healed sites using the flush implant technique. Eleven have been placed in mandibular bicuspid and molar areas and six have been placed in maxillary anterior and bicuspid areas. A mucoperiosteal flap was used, wherever possible. Three of the seventeen implants have failed, all of these failures were in the posterior mandibular area. The time until failure ranged between 3 weeks and 41 weeks. There was no apparent consistency to these failures.

The remaining 14 implants have been implanted for an average of 43 weeks. The range of implant times is from 6 weeks to 1.29 years. Eight of these implants have not yet been restored either due to insufficient ingrowth time or patient inavailability.

Four of these implants have been restored. The average restoration time is 25 weeks. The average implant time is 1.19 years. Three of these implants are in maxillary anterior healed sites. The fourth is in a mandibular molar, fresh extraction site. It is significant to note that none of these implants show any sign of mobility, or significant bone loss. Also none of these implants were ever evaluated as being mobile during the prerestoration period. This finding is dramatically different than the situation seen in Group I or II patients.

Figure 10A is one example of an implant placed using the flush implant technique. In this case, the implant is barely visible after being deeply placed in the socket formed in the fresh extraction site. This implant was not covered with a flap. Figure 10B shows the radiograph taken the day of surgery. Note voids about the implant. The pre-existent lamina dura of the site is visible. The top of the implant is flush with the alveolar crest.

Figure 11A illustrates the same implant at 1 year post implant. The implant is rigid and functional. Note some degree of gingival recession on the buccal aspect. Figure 11B is a radiograph taken at the same time. Note



(A)



(B)

FIGURE 10. EXAMPLE OF FLUSH IMPLANT TECHNIQUE IN HUMAN

The clinical photograph and radiograph show the placement of a root in a fresh extraction site. Note that the root is flush with the alveolar ridge. Patient 81R1, 4/1/81.



(A)

(B)

FIGURE 11. CLINICAL PHOTOGRAPH AND RADIOGRAPH OF PATIENT 81R1,
ONE YEAR POST IMPLANT

The root has been reconstructed. There has been some gingival recession. The radiograph indicates dense bone around the bottom of the implant. There appears to be some loss of alveolar bone height at the top. The implant is rigid, gingival health is excellent, and the implant is functional.

that compared to the previous figure, the density of bone has increased especially at the apical end of the implant. The voids around the implant observed post surgery have filled dramatically. This filling is especially apparent distal to the implant. Mesial to the implant much of the preexisting lamina dura is still present. There has been some loss of vertical bone height at the alveolar crest. This implant is totally rigid, functional, and is serving the patient as a useful prosthesis.

An example of anterior maxillary implants are shown in Figures 12 and 13. Figure 12A is a radiograph of the implant in Area 10. The implant was covered with a mucoperiosteal flap. The patient was allowed to wear a flipper for the healing period. In this case, 9 months was allowed to elapse before reconstruction. Figure 12B is a radiograph of the final restoration. There is no radiolucency around the implant, however, there also does not appear to be any increase in radiodensity. This observation is not unusual, since the implant was just placed in function at the time of this radiograph. The implant is rigid, functional, gingival health is good, and it is serving as a functional prosthesis. Figure 13 shows the clinical appearance of another upper anterior case. Figure 13A, the upper clinical photograph shows the post and core in place, 9 months post implant. Figure 13B shows the final restoration. This implant is rigid and functional.

Two other patients in this group exhibited a clinical history different from any we have observed in the past. The patients had totally immobile implants at the time of post and core placement; however, shortly thereafter, they developed severe mobility of their implants. In both cases, the gold post and cores were cut off flush with the implant, and the implants were tapped deeper into the socket. The tapping restabilized the implants. We are now observing these two implants to ascertain if they will remain stable. A possible explanation of this behavior is that the large increase in stresses on the implant at the time of restoration was too great for the density of bone formed. The radiographs of these patients did not demonstrate radiolucency or bone loss prior to reconstruction. It is also possible that bone healing is extremely slow or delayed. For example, Figure 14 illustrates a series of radiographs from a patient which demonstrated a loss of bone and delayed healing. Figure 14A shows the implant one week post-surgery. The



(A)

(B)

FIGURE 12. RADIOGRAPHS OF UPPER ANTERIOR IMPLANT IN PATIENT 81R3

The first radiograph shows the implant at the time of surgery. The implant is flush with alveolar bone. The lower radiograph shows the same implant restored.

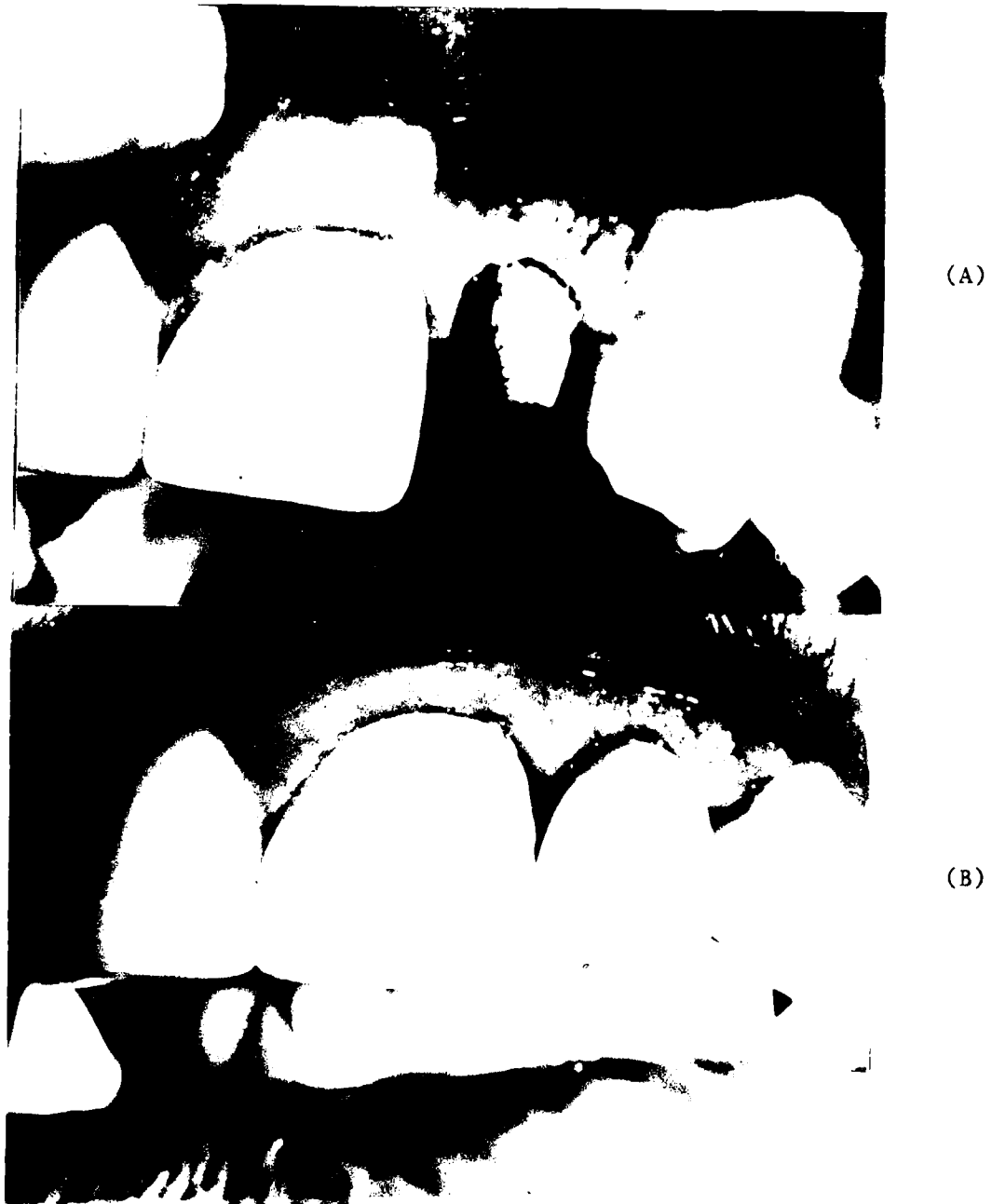


FIGURE 13. CLINICAL PHOTOGRAPHS OF UPPER ANTERIOR IMPLANT (A10)
IN PATIENT 81R3

These photographs show the patient at 9 months post-surgery. The upper view shows the post and core cemented in place and the lower photograph shows the final restoration. This implant is rigid and functional.



(A)

(B)

(C)

FIGURE 14. RADIOGRAPHS OF IMPLANT EXHIBITING BONE LOSS AND DELAYED HEALING

The upper radiograph (A) shows the implant one week after surgery. Note that the implant is flush with the alveolar crest and well approximated to surrounding bone. The second radiograph (B) shows a definite radiolucency around the implant and loss of alveolar bone height. The implant was allowed to remain non-functional for an extended period of time. At one year (C), the situation has reversed itself. Good bone formation is seen around the bottom of the implant; however, there is still alveolar bone loss.

implant appears well placed, flush with the alveolar crest. There are no large voids, the implant appears closely adapted to adjacent bone; however, at 12 weeks post-implant (Figure 14B), definite radiolucency is forming about the implant and the implant was considered a potential failure.

The implant was reexamined periodically. At 1.06 years post-implant, the situation has reversed itself. Bone is now formed lightly about the apical end of the implant; however, there is some loss of vertical bone height. It is important to note that the implant was never placed in function, and it remained fairly well isolated from stresses in the oral cavity. This is different from the situation present in Group I and Group II implant studies. As long as motion (strain) is minimal, the replacement of a previously resorbed area with bone tissue is consistent with current knowledge of bone healing.⁽²¹⁾

Parametric Analysis

To better understand the mechanics of the dental implant in bone, a mathematical analysis of the implant has been undertaken. The method being used is finite-element analysis. This laboratory, as well as the biomechanics community in general, has widely used this mathematical technique on biological problems.⁽⁹⁾ Presented in this report is the first version of the model now being developed.

Figure 15 is the grid representation of the mathematical model. For simplicity, only one-half of the implant is shown in cross section. The relatively thin cortical plates of bone and the thin layer of bone below the implant are characteristics normally noted histologically. The outline of the implant indicates the area which is ceramic. The post area and the portion above the top of the implant is gold. The remaining area is bone.

The following elastic moduli were used in the model: ceramic, 54.53×10^6 psi; gold, 11.92×10^6 psi; and bone, 1.98×10^6 psi. Using these constraints, the data shown in Table 3 were computed for an axial (occlusal) static load of 25 pounds. These calculations are for the smallest implant (4 mm x 4 mm). This size implant would have the highest stresses under the serrations because it has the smallest surface area of serrations to

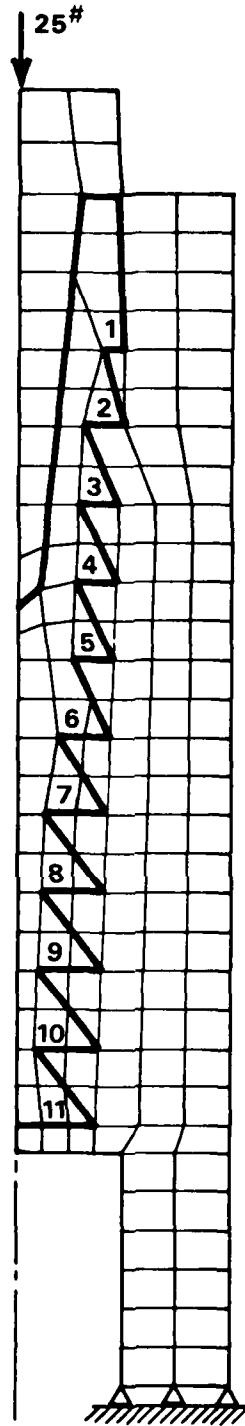


FIGURE 15. GRID REPRESENTATION OF AXISYMMETRIC MODEL OF 4 X 4 MM IMPLANT

In this figure, only one-half of the implant system is shown. The heavy line shows the outline of the ceramic implant.

distribute the load. Also, the wall thickness of ceramic would be the thinnest and most critical in this size implant.

TABLE 3. AXISYMMETRIC MODEL WITH 25-POUND AXIAL LOAD

| Serration
| Maximum Axial Stress (psi) | | Serration
Depth (mm) |
|----------------|----------------------------|------|-------------------------|
| | Implant | Bone | |
| 1 | -1223 | -104 | 0.435 |
| 2 | -1089 | -167 | 0.763 |
| 3 | -1137 | -147 | 0.761 |
| 4 | -2414 | -145 | 0.759 |
| 5 | -2093 | -137 | 0.762 |
| 6 | -1510 | -224 | 0.979 |
| 7 | -1701 | -313 | 1.196 |
| 8 | -1918 | -285 | 1.196 |
| 9 | -1733 | -235 | 1.197 |
| 10 | -1318 | -194 | 1.196 |
| 11 | - 691 | 21 | 2.956 |

Note in Table 3 that the maximum axial stress in the bone under each serration is well below the 400 psi design limit.⁽⁹⁾ That is a range which does not result in bone resorption, but appears to facilitate bone remodeling. The negative sign is used by convention to denote compression. Note that the bone stress is maximum about three serrations below the bottom of the gold post and decreases somewhat regularly in both directions from that point. Also, bone stresses under the smaller serrations at the top of the implant are below the 400 psi design limit despite the smaller serration sizes. A higher stress might be expected under a smaller serration, all other conditions being

equal. The model predicts a net tension in the bone at the bottom of the implant. This is not unreasonable in light of the thin layer of bone in that location.

Since the finite element code used for the axisymmetric case only produces element centroid stresses, these are not necessarily the maximum stresses. The more complete three-dimensional model now under development will predict stresses at up to 13 locations along the bottom edge of a serration. Consequently, the more sophisticated model will give a more accurate representation of the stress distribution.

CONCLUSIONS

The animal research to date indicates a high probability of success for the implant system. Loss of stability via bone loss or infection has not occurred in any animal implant that has become stable. Current failures in baboons have been caused by fracture of ceramic at the approximate level of the alveolar crest. Fractures appear to be clustered in implants produced in 1976. Low-quality ceramic material is suggested. Contemporary materials now being used have vastly improved structural properties, and failures have not occurred with these newer materials.

The baboon continues to provide valuable information as to long-term success of implants. The longest term implants provide proof that successful function of serrated ceramic implants is possible for up to seven years. There has been no evidence of any deleterious effect of the implant upon the health of the animal by any of the indices measured.

This baboon colony is a unique research resource in that it is the only known long-term animal trial of ceramic implants. The clinical chemistry, clinical health, and eventual necropsy data (both gross and microscopic) will be relevant to the human situation. One apparent drawback to the baboon model is the ease and rapidity of bone ingrowth relative to the human. However, once ingrowth has occurred, the baboon model provides a "worst case" test for the implant. Relatively high loadings and lack of oral hygiene are a severe test for the implants.

The human studies initially did not prove as successful as the baboon studies. Loss of initial stability of the implant appears to affect the long-term success. Even though all human implants were implanted stable by virtue of an interference fit with the bone, this stability was lost within the first month. In the successful cases, the relative degree of mobility reversed and continually decreased until minimal. However, in many of the implants, mobility slowly increased over a period of 1 to 2 years until failure was inevitable. In light of the loss of initial stability different stabilization techniques were attempted to rectify the situation. The most recently employed technique of placing the implant flush with alveolar bone has produced a dramatic change in the results. The extra isolation from

mechanical stresses appears to have made a significant difference in the outcome of the implant studies. Further implant studies and continued observation of present implants is required to validate this statement.

The initial ingrowth phase continues to be the most critical phase of the procedure. If initial stability is maintained throughout the ingrowth and reconstruction phase; the long-term prognosis for success is excellent. In humans, the success appears to be related to the implant site. In our experience, anterior maxillary implants appear to have a high success probability, whereas posterior mandibular sites have a lower success probability. This site specific probability of success was not apparent in the baboon studies.

RECOMMENDATIONS

It is recommended that the human study be continued to ascertain if the dramatically increased apparent success observed with flush placement of the implants can be continued. The maintenance of initial stability in a high percentage of this last group of implants is encouraging. Since initial stability appears to be a critical factor, techniques to facilitate initial stability should be incorporated. To this end, evaluation of plug gauges and files shaped to the implant size should be evaluated in the next series of implants.

It is recommended that the parametric analysis of the implant in bone be continued. This study will assist in indicating areas where the design can be improved. Also, potential structural weaknesses in the design can be evaluated.

Further, it is recommended that the long-term animal evaluation be completed. Within the next several months, the average implant function time in baboons will be 5 years. Some specimens will have been in function for nearly 8 years. At this time, an in-depth histopathologic analysis of all major organ systems should be performed. Also, a careful analysis of the implant-bone interface should be undertaken.

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